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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/051,663      | 01/18/2002  | Vernon M. Ingram     | M00656/70071 (JRV)  | 3098             |

23628            7590            04/28/2003  
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| EXAMINER |
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CELSA, BENNETT M

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1639

DATE MAILED: 04/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

*File Copy*

## Office Action Summary

Application No.

10/051,663

Applicant(s)

Ingram et al.

Examiner

Bennett Celsa

Art Unit

1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on \_\_\_\_\_
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1, 7, 8, 10, 12-16, 22, 24, 26-29, and 31-41 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1, 7, 8, 10, 12-16, 22, 24, 26-29, and 31-41 are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      6)  Other: \_\_\_\_\_

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## DETAILED ACTION

### *Status of the Claims*

Claims 1, 7, 8, 10, 12-16, 22, 24, 26-29, and 31-41 are currently pending.

NOTE: the location of the present application is ART UNIT 1639.

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

*and*

- I. Claims 1, 7 and 16 (in part), 8, 10, 15, 22, 24 ~~and 25~~ are drawn to a method of treating neural depolarization condition (e.g. Alzheimers) by administering a tyrosine kinase inhibitor to decrease membrane neural depolarization, classified in class 514, subclass 313.
- II. Claims 1, 7 and 16 (in part), 12, 15, and 26, drawn to a method of treating neural depolarization condition (e.g. Alzheimers) by administering a chloride channel antagonist to decrease membrane neural depolarization, classified in class 514, subclass 408.
- III. Claims 1, 7 and 16 (in part), 13, 15, and 27, drawn to a method of treating neural depolarization condition (e.g. Alzheimers) by administering a dopamine receptor agonist to decrease membrane neural depolarization, classified in class 514, subclass 456 .
- IV. Claims 1, 7 and 16 (in part) 14-15 and 28, drawn to a method of treating neural depolarization condition (e.g. Alzheimers) by administering an alpha2-adrenergic receptor antagonist to decrease membrane neural depolarization, classified in class 514, subclass 283.

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V. Claim 29 drawn to a composition comprising a compound that decreases neuronal membrane depolarization and a compound that decreases neuronal calcium influx, classified in various classes/subclasses upon the election of compound species .

VI. Claim 31 drawn to a composition comprising a compound that decreases neural membrane depolarization and a secretase inhibitor, classified in various classes/subclasses upon the election of compound species .

VII. Claim 32 drawn to a composition comprising a compound that decreases neuronal cell calcium influx and a secretase inhibitor classified in various classes/subclasses upon the election of compound species .

VIII. Claim 33 drawn to a method of treating Alzheimer's disease by administering an AB vaccine and a neuronal membrane depolarization inhibiting compound , classified in class 424, subclass 184.1+ .

IX. Claim 34 drawn to a method of treating Alzheimer's disease by administering an AB vaccine and a composition comprising a compound that decreases neuronal membrane depolarization and a compound that decreases neuronal calcium influx, classified in class 424, subclass 184.1+ .

X. Claim 35 drawn to a method of treating Alzheimer's disease by administering an AB vaccine and a composition comprising a compound that decreases neuronal membrane depolarization, a compound that decrease neuronal calcium influx and a secretase inhibitor, classified in class 424, subclass 184.1+ .

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XI. Claim 36 drawn to a method of treating Alzheimer's disease by administering an AB vaccine and composition comprising a compound that decreases neuronal membrane depolarization, and a secretase inhibitor, classified in class 424 subclass 184.1+ .

XII. Claim 37 drawn to a method of treating Alzheimer's disease by administering an AB vaccine and composition comprising a compound that decreases calcium influx and a secretase inhibitor, classified in class 424 subclass 184.1+ .

XIII. Claim 38 drawn to a method for treating Alzheimer's disease comprising administering a composition comprising a compound that decreases neuronal membrane depolarization and a compound that decreases neuronal calcium influx, classified in various classes/subclasses upon the election of compound species .

XIV. Claim 39 drawn to a method for treating Alzheimer's disease comprising administering a composition comprising a compound that decreases neuronal membrane depolarization, a compound that decreases neuronal calcium influx and a secretase inhibitor, classified in various classes/subclasses upon the election of compound species .

XV. Claim 40 drawn to a method for treating Alzheimer's disease comprising administering a composition comprising a compound that decreases neuronal membrane depolarization and a secretase inhibitor, classified in various classes/subclasses upon the election of compound species .

XVI. Claim 41 drawn to a method for treating Alzheimer's disease comprising administering a composition comprising a compound that decreases neuronal cell calcium influx and a secretase inhibitor, classified in various classes/subclasses upon the election of compound species .

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The inventions are distinct, each from the other because of the following reasons:

1. Composition Inventions V-VII are drawn to different compositions comprising different compounds which differ due to differences in chemical structure, properties and are capable of separate manufacture and/or use and which require different and separately burdensome manual/computer sequence, structure and bibliographic searches.
2. Method Inventions I-IV and VIII-XVI are distinct, each from the other since the methods differ in employing compounds/compositions which comprise patentably distinct compounds due to differences in chemical structure, properties and are capable of separate manufacture and/or use and which require different and separately burdensome manual/computer sequence, structure and bibliographic searches
3. Inventions (V-VII) and (XIII-XVI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product e.g. diagnostic use.
4. Because these inventions are distinct for the reasons given above and
  - a. have acquired a separate status in the art as shown by their different classification;
  - b. required different and separately burdensome manual/computer structure/sequence/bibliographic searches in patent/literature databases.

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c. because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***ELECTION OF SPECIES (FOR GROUPS I-XVI ABOVE)***

5. This application contains claims directed to the following patentably distinct species of the claimed invention: different classes of compounds e.g. tyrosine kinase inhibitor; a chloride channel antagonist; dopamine receptor agonist ; an alpha2-adrenergic receptor antagonist mGluR1 antagonist; compounds that decrease calcium influx; secretase inhibitors and combinations thereof.

These different classes of compounds each contain patentably distinct compounds due to differences in chemical structure, properties and separate manufacture and/or use which would require separately burdensome manual/computer bibliographic searches.

Upon the election of an Invention, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species (e.g. a single compound) for each class of compound and a corresponding chemical structure for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)

April 24, 2003

BENNETT CELSA  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Bennett Celsa".